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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,542	01/07/2002	Charles E. Birse	PA002P1	4848
22195	7590	04/15/2004		
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			EXAMINER MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 04/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,542	BIRSE ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-25. Claims 1-10, 14-15, 21-22, are drawn to a nucleic acid encoding a protein of amino acid sequence of set forth in Table I, a vector, a host cell and a process for producing the receptor polypeptide, classified in Class 435, subclass 69.1.

Groups 26-50. Claims 11-12, 16, are drawn to a polypeptide of amino acid sequence of set forth in Table I, classified in Class 530, subclass 350.

Groups 51-75. Claim 13 is drawn to an antibody to a polypeptide of amino acid sequence of set forth in Table I, classified in Class 530, subclass 387.9.

Groups 76-100. Claim 17 is drawn to a method of treatment by administering the polypeptide of amino acid sequence of set forth in Table I, classified in Class 514, subclass 2.

Groups 101-125. Claim 18 is drawn to a method of treatment by administering the nucleic acid encoding the polypeptide of amino acid sequence of set forth in Table I, classified in Class 514, subclass 44.

Groups 126-150. Claim 19, is drawn to a method of diagnosing a pathological condition using the nucleic acid encoding the polypeptide of amino acid sequence of set forth in Table I, classified in Class 435, subclass 6.

Groups 151-175. Claim 20, is drawn to a method of diagnosing a pathological condition using an antibody to the polypeptide of amino acid sequence of set forth in Table I, classified in Class 435, subclass 7.1.

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Groups 176-200. Claim 21 is drawn to a method for identifying a compound that modulates the activity of the polypeptide of amino acid sequence of set forth in Table I and the compound obtained thereby, classified in Class 435, subclass 7.1.

Groups 201-225. Claim 23 is drawn to a method for identifying an activity in a biological assay by expressing the nucleic acid encoding the polypeptide of amino acid sequence of set forth in Table I, class and subclass undeterminable.

Claim 24 is drawn to a product produced by the method of claim 20. However, claim 20 is drawn to a method of diagnosing a pathological condition using an antibody to the polypeptide of amino acid sequence of set forth in Table I. It is unclear to the Examiner what product is being claimed. Therefore, this claim has not been excluded from the Restriction requirement.

Should any one of the Groups from 1-225 be elected, Applicant is required to select one polypeptide (one amino acid sequence) as set forth in Table I from SEQ ID NO:Y. Once one polypeptide sequence is selected, all other sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-25, 26-50, 51-75, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotides of inventions 1-25 can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific proteins of interest. The proteins of inventions 26-50 can be used as probes, or used therapeutically or diagnostically, e.g. in screening. The antibodies of inventions 51-75 can be used to obtain the polynucleotides of Groups 1-25, and can also be used in diagnostics, e.g. as a probe in immunoassays. Each of the

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polynucleotides of inventions 1-25 can be used to produce the specific polypeptides of Groups 26-50, respectively. The polynucleotide of Group I can only be used to produce the protein of Group 26 but not the proteins of Groups 27-50.

Inventions I-25 and 26-50 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions 26-50 and 76-100, 176-200, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 26-50 can also be used as an antigens in the production of specific antibodies.

Inventions I-25 and 101-125, 126-150 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 1-25 can also be used in production of the protein of interest.

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Inventions 51-75 and 151-175 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 51-75 can also be used in immunochromatography.

Inventions 1-25, 76-100, 151-175, 176-200, 201-225 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 26-50, 101-125, 126-150, 151-175, 201-225, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 51-75 and 76-100, 101-125, 126-150, 176-200, 201-225, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

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Inventions 76-225 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
April 1, 2004